I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 5/3/04 Signature: Rebecca V (Rebecca McElroy)

Docket No.: 511582001621
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Daniel E. AFAR et al.

Application No.: 10/010,667

Art Unit: 1642

Filed: December 6, 2001

Examiner: Gary B. Nickol, Ph.D.

For: PEPTIDES DERIVED FROM STEAP 1
(as amended)

DECLARATION OF JEAN M. GUDAS, PH.D.

UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Jean M. Gudas, declare as follows:

1. I am currently Director of Antibody Development at Agensys, Inc., in Santa Monica, California. I am responsible for supervising the generation of antibodies to proteins contemplated as targets for antibody-based diagnosis and therapy in tumors. I have extensive experience in scientific matters related to oncology and have been practicing in this field for almost 20 years, since I received my Ph. D. in Public Health/Environmental Health Sciences from UCLA in 1985. A copy of my *curriculum vitae* is attached as Exhibit A.

2. The above-referenced application concerns, among other things, a protein designated STEAP-1 that is produced in various cancers. The protein and certain of its fragments are able to raise antibodies that are immunoreactive with this protein. We have found that in prostate cancer, administration of monoclonal antibodies immunoreactive with STEAP-1 both inhibit the growth of the tumor and lower the levels of PSA secreted into the bloodstream.

3. Specifically, we conducted an experiment wherein mice were injected with 2×10^6 LAPC9 prostate tumor cells subcutaneously. Six groups of 10 mice each were used. In all cases, the mice were injected with the LAPC9 cells and then treated according to various protocols. In each group, the mice were injected with test solutions two times per week for a total of 12 injections wherein the last day of injection was day 40. The first injection was on the same day as the injection of tumor cells. Injection was by the intraperitoneal route. Group I received PBS injections, Group II received control anti-KLH antibody injections, Group III received the anti-STEAP-1 antibody 120.545 at 500 μg per dose; Group IV received 120.545 antibody at 100 μg per dose; Group V received anti-STEAP-1 antibody 92.30 at 500 μg per dose and Group VI received 92.30 antibody at 100 μg per dose. Tumor volume was monitored over the treatment period.

4. Exhibit B shows the results. As indicated, tumor growth in the controls (Groups I and II) and at dosages of 100 μg of the two antibodies tested was consistently higher than tumor growth exhibited when either antibody was administered at 500 μg per dose. These results are shown in a different form in Exhibit C which shows, on the left, median tumor volume on day 40. It is clear that administration of either STEAP-1 antibody is effective in decreasing tumor volume.

5. Similarly, the right hand graph of Exhibit C demonstrates that both anti-STEAP-1 antibodies reduce the levels of PSA in the mouse.

6. I conclude from these results that antibodies raised against STEAP-1 are effective in inhibiting the growth of prostate tumors.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Executed at Santa Monica, California, on 29th April 2004.

Jean M. Gudas